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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/069,673

10/15/2002

Peter Frank Ekhart

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EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/069,673	Applicant(s) EKHART ET AL.	
	Examiner Jennifer Kim	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 5, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed on February 5, 2008 have been received and entered into the application.

Response to Arguments

Applicants' arguments have been fully considered but they are not persuasive. Applicants essentially argue that the claimed composition is prepared by first mixing the active compound with a water-immiscible liquid (i.e. an oil such as vegetable oil) and then mixing the solid in oil suspension with water or an aqueous carrier in such a manner that the mixture of active compound and water-immiscible liquid has a density which is near to the density of water and suspending the mixture in an aqueous carrier to form an emulsion which results in a suspoemulsion. This is not found persuasive because the instant claims are not "product-by-process" claims, therefore, Applicants arguments regarding how the composition is prepared by the steps above is irrelevant. Further, Dick et al. teach that mebendazole can be formulated in suspensions comprising water and can be added to animal feed or drinking water. The optimization of liquid density, the pharmaceutical forms, e.g., suspoemulsion, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and

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modes of administration. The Examiner has deleted the statement about glycerin as a water-immiscible liquid, however, the rejection still holds because Lur'e et al. teaches that formulations of mebendazole in the specific water immiscible liquid and that the Dick et al. teach that the mebendazole can be delivered in water. Therefore, the cited references show the common adjuvants useful for formulating mebendazole and it is obvious for the artisan to combine the adjuvants to formulate a veterinary composition comprising mebendazole. The formulations in combination with these adjuvants suggested by the prior art is obvious, as indicated in consideration of the 2007 Supreme court decision in *KSR V TELEFLEX* @82 USPQ 2d @1385. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

It is suggested that Applicants submit a declaration to clearly establish a surprising and unexpected result using Applicants teaching.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dick et al. (FR 2336931) of record in view of Lur'e et al. (Meditsinskaya Parazitologiya I Parazitarnye Bolezni (1987, abstract).

Dick et al. teach that new pharmaceutical compositions containing mebendazole can be formulated in suspensions comprising water and can be added to an animal feed

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or drinking water. (abstract). Dick et al. teach compositions comprising mebendazole, water, glycerin, and stabilizing agents. (page 6, example 6). Dick et al. teach that compositions can be administered orally to animals in liquid formulation. (page 2, lines 25-33).

Dick et al. do not teach the specified density and the specified ratio of the active agents, and the particle size.

Lure'e et al. teach that mebendazole (a benzimidazole active compound) can be formulated with sunflower, corn, mustard, olive or apricot oils. Lur'e et al. teach that the sunflower oil was the most effective vehicle and it increased bioavailability and prolonged the maintenance of therapeutic levels of mebendazole in the blood of experimental mice. (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made prepare Dick et al's composition for veterinary use through a water distribution system by incorporating sunflower oil of Lur'e et al. because Lure'e et al. teach that sunflower oil was the most effective vehicle and it increases bioavailability and prolonged the maintenance of therapeutic levels of mebendazole and because Dick et al. teaches that mebendazole composition can be administered to animals in a liquid formulation and because Dick et al. teach that compositions can be added to an animal feed or drinking water. One would have been motivated to make such a modification in order to increase the bioavailability of mebendazole in Dick et al's composition. Further, one would have been motivated to add the Dick et al's composition in animal drinking water in order to advantageously administer mebendazole liquid formulation while

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satisfying the thrusts. There is a reasonable expectation of successfully administering mebendazole liquid formulation of Dick et al. with sunflower oil and utilizing water distribution system such as water supply because Dick et al. teaches that the composition comprising mebendazole can be administered successfully in drinking water and that sunflower oil is the most effective vehicle for mebendazole as taught by Lure' et al. The ratios of active agents to be used, the density the pharmaceutical forms, e.g., suspoemulsion, emulsion, etc; mode of administration, the specific particle size are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and it is within the general practice to discover the optimum or workable ranges involves only routine skill in the art.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Kim/

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Primary Examiner, Art Unit 1617

Jmk
April 23, 2008